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# Section. 5 510(k) Summary

AUG 14 2008


Company Name: Cardiovascular Systems, Inc.
651 Campus Drive
St. Paul, MN 55112

Contact: David D. Brooke

Phone: (651) 259-2061

Fax: (651) 259-1696


Summary Date: July 7, 2008

Trade Name: Diamondback 360°™ Orbital Atherectomy System with Sidewinder Shaft

Common Name: Peripheral Atherectomy Device

Classification Name: Peripheral Atherectomy Catheter (21 CFR 870.4875; Product Code: MCW)

Predicate Device:

510(k) Number: K072748
Manufacture: Cardiovascular Systems, Inc.
Trade Name: Diamondback 360°™ Orbital Atherectomy System

510(k) Number: K071350
Manufacture: Cardiovascular Systems, Inc.
Trade Name: Diamondback 360°™ Orbital Atherectomy System

## 5.1 Description of Device

The Diamondback 360°™ Orbital Atherectomy System (OAS) with Sidewinder Shaft is intended for use in the treatment of peripheral artery and A-V shunt stenosis.

OAS provides a method of removing stenotic material from peripheral arteries and A-V shunts. OAS applies a diamond coated, eccentrically rotating cutting surface to ablate stenotic material. The resulting particles of removed stenotic material are very small and can be absorbed by the body.

The Diamondback 360° Orbital Atherectomy System consists of the following three significant components:
1) Orbital atherectomy device, with biased shaft
2) Orbital atherectomy controller, and

3) Atherectomy guidewire.

This 510(k) is for the same device with modifications to the shaft configuration of the orbital atherectomy device for improved sanding efficiency.

## 5.2 Intended Use

The Diamondback 360°™ Orbital Atherectomy System is a percutaneous orbital atherectomy system indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and who are acceptable candidates for percutaneous transluminal atherectomy.

The Diamondback 360°™ Orbital Atherectomy System is also indicated for removal of stenotic material from artificial arteriovenous dialysis fistulae (A-V shunts).

## 5.3 Technology

The Diamondback 360°™ Orbital Atherectomy System with Sidewinder Shaft provides a method of removing occlusive atherosclerotic or stenotic material. This OAS applies a diamond coated, eccentrically rotating cutting surface mounted on a bias-formed shaft to ablate stenotic tissue. The resulting particles of removed stenotic tissue are very small and can be absorbed by the body. This same technology was cleared to market for use in peripheral arteries in 510(k) K071350, for use in A-V shunts in 510(k) K071427 and for a solid crown configuration per K072748.

## 5.4 Conclusions

The Diamondback 360°™ Orbital Atherectomy System with Sidewinder Shaft is substantially equivalent to the predicate devices. Laboratory and animal tests were performed to support the safety profile of the modification to the Orbital Atherectomy System. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 14 2008

Cardiovascular Systems, Inc.
c/o Mr. David Brooke
Sr. Regulatory Manager
651 Campus Drive
Saint Paul, MN 55343

Re: K081944
Diamondback 360° Orbital Atherectomy Device System with Sidewinder Shaft
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II (two)
Product Code: MCW
Dated: August 7, 2008
Received: August 8, 2008

Dear Mr. Brooke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Section. 4 Indications For Use Statement

**510(k) Number:** K081944

**Device Name:** Diamondback 360° Orbital Atherectomy System with Sidewinder Shaft

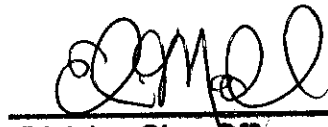
**Indications for Use:**

The Diamondback 360°™ Orbital Atherectomy System is a percutaneous orbital atherectomy system indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and who are acceptable candidates for percutaneous transluminal atherectomy.

The Diamondback 360°™ Orbital Atherectomy System is also indicated for removal of stenotic material from artificial arteriovenous dialysis fistulae (A-V Shunts).

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 801 Subpart C)

**Concurrence of CDRH, Office of Device Evaluation (ODE)**



**(Division Sign-Off)**
**Division of Cardiovascular Devices**

**510(k) Number** K081944